97TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 97-625

RISK ANALYSIS RESEARCH AND DEMONSTRATION ACT OF 1982

JUNE 24, 1982.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. FUQUA, from the Committee on Science and Technology, submitted the following

REPORT

[To accompany H.R. 6159]

[Including cost estimate of the Congressional Budget Office]

The Committee on Science and Technology, to whom was referred the bill (H.R. 6159) to establish a program under the coordination of the Office of Science and Technology Policy for improving the use of risk analysis by those Federal agencies concerned with regulatory decisions related to the protection of human life, health, and the environment; having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

On page 2, strike subsection "(4)", lines 13 and 14, and renumber the following subsections accordingly.

PURPOSE OF THE BILL

The purpose of the bill is to establish a coordinated, 30-month program of research and demonstration on the methodologies, applications, and potential limitations of risk analysis in the regulatory decisionmaking process. Nine Federal agencies are specifically included for participation in the research and demonstration program, which will: (1) improve our understanding of risk and comparative risk analysis; (2) aid in developing standards for its application; (3) identify areas that may require additional research; and (4) promote public understanding of risk and the means of its quantification.

This proposed legislation would, if enacted, guide efforts at improving the understanding and use of risk analysis and comparative risk analysis by the Federal regulatory agencies. It would also establish an oversight role for the Congress as these decisionmaking tools

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continue to be developed and applied. At present, there are numerous agencies grappling with the concept of risk and its management, at widely varying levels of sophistication. At the same time, there is little Administration-wide coordination, and the Congress has not addressed, in generic terms, the definition of risk analysis, or more critically, the question of just how risks are best assessed, quantified and analyzed. Building consistency and standards of quality into Federal applications of risk analysis is long overdue, in the Committee's view. Risk analysis should be viewed as a developing technology to assist in the regulatory decisionmaking process, and the research and demonstration program specified in this Act is designed to insure that we have the experience and know-how to use it effectively and wisely.

Placing risks into perspective, so that they can be best weighed with other factors in the regulation of hazards, is the long-term goal of developing the techniques of comparative risk assessment. As it is, there are intense pressures on regulators from a wide array of interested parties—from the consumer and environmental groups, to the media and vested commercial interests.

The techniques of risk and comparative risk analyses that would be researched under this legislation will eventually assist the regulatory agencies to set priorities and focus on those issues that present the greatest hazard to our health and environment.

With respect to the question of quantitative applications of risk analysis, it is evident to the Committee that caution should be exercised continuously and well into the future, and that strenuous scientific peer review should be applied to a risk analysis before the results or conclusions of that analysis becomes a key factor in a quantitative regulatory decision. Even though it is desirable to strengthen and experiment with the use of risk analysis, it would be counterproductive to impose an incomplete or immature science as the dominant factor in public policy decisions. This legislation has as its goal the improvement of the science underlying the tool of risk analysis, so that acceptance of the approach is judged to be warranted by qualified scientists and policymakers.

IMPLEMENTATION OF THE BILL

This bill would provide coordination for research on the methodologies of risk and comparative risk analyses, and would promote the performance of prototype demonstrations within Federal agencies. It is intended to complement and give greater Congressional impetus to risk analysis activities presently ongoing within the Federal agencies.

These activities would be overseen and guided by the Office of Science and Technology Policy and would be coordinated by the Office of Management and Budget. OMB will analyze and synthesize the agencies' results and suggestions into a report to be submitted to the Congress within 30 months of the legislation's passage. By mandating an OSTP role and the submission of a comprehensive report on the status of risk analysis, Congress will hopefully be in a better position to assess what next should be done to improve the use of risk analysis.

The intent of the bill is not to mandate unjustified intrusions into

the regulatory decisionmaking process. It may or may not turn out to be the case that a uniform approach to the use of risk and comparative risk analysis is desirable. This is one question upon which the final report would be expected to shed some light.

The scientific tools that this legislation promotes, will, in the final analysis, save resources at the regulatory agencies. It is the concept, the approach itself, and its potential usefulness that the Committee intends to explore further. Neither risk analysis nor this legislation represent ends in themselves.

PROGRAM PARTICIPANTS

The agencies who would participate are: Food and Drug Administration, Environmental Protection Agency, Occupational Safety and Health Administration, the Food Safety and Inspection Service of the Department of Agriculture, Nuclear Regulatory Commission, Department of Energy, Consumer Product Safety Commission, Federal Aviation Administration, and the Department of Transportation. This list is not all inclusive but it is intended to bring into the program those Federal agencies with statutory bases for regulating risks to human life, health, or the environment.

RESEARCH

The agencies which are program participants would recommend to the Office of Science and Technology Policy areas of research intended to improve and develop new techniques for measuring, gathering, analyzing, and evaluating data necessary to complete risk assessments and evaluations, with particular emphasis on the use of comparative risk in risk evaluation.

The National Science Foundation would recommend to OSTP a program of research directed at strengthening the basic and applied sciences required for Federal agencies to better utilize risk analysis. The OSTP would establish a mechanism for coordinating these separately recommended research programs.

DEMONSTRATION PROJECTS

Each program participant would undertake a prototypical risk analysis study. These studies, to be completed within 2 years following the bill's enactment into law, would include: (1) a comparison of the risks from alternative courses of action; (2) a delineation between scientific and policy judgments; (3) an identification of specific assumptions and uncertainties that underlie the problem; (4) an identification of limitations placed on the analysis due to relevant organizational and statutory constraints; (5) an identification of specific tradeoffs posed in the particular risk analysis; (6)) suggestions of how additional information, or changes in statutory language could change the strategy chosen to cope with this problem; (7) a discussion of how comparative risk analysis could be utilized to make the public aware of the relevance of the decisions; and (8) a delineation of information concerning the different levels of risk to health and welfare among subgroups of the population.

REPORTS

The bill calls for two reports to be issued by OMB within 12 and 30 months following its enactment into law. The first report would essentially present a program plan which shall include: (1) a review of the risk analyses presently being carried out within the Federal regulatory agencies and how they are used in the decisionmaking process; (2) a review of the risk analysis research being carried out and the procedures for linking this research to the decisionmaking process; (3) a brief review of risk analysis and related research existing outside the Federal government; (4) specific ideas for research to be conducted within Federal agencies and recommendations for the funding of such research outside such agencies by the Federal regulatory agencies, the National Science Foundation, and the National Institutes of Health; (5) recommendations for a coordinating mechanism to transmit and share research results among interested parties; (6) a program plan for the prototypical risk analysis demonstrations; (7) identification of areas where the use of risk analysis is limited or prohibited by current law, regulation or statute; and (8) recommendations for increasing public awareness of risk.

The final 30-month report would serve to bring the Congress up to date on the success or lack thereof of the entire research and demonstration program. It would include: (1) a summary of the findings made pursuant to the first report; (2) an analysis of agencies' risk analysis procedures or capabilities as evidenced by the prototype studies mandated by this bill; (3) recommendations for future research necessary to achieve the bill's purposes; (4) recommendations for legislative and non-legislative changes, including organizational changes, needed to implement and facilitate the use of risk analysis within Federal agencies; (5) recommendations that will result in the improved transfer of risk-related research and information among interested public and private parties; and (6) recommendations for improving and increasing public understanding and appreciation of risk and regulatory decisions.

Legislative Background Work on Risk Analysis

Over the last several years, the Committee on Science and Technology has explored ways to improve the scientific input into regulatory decisions that involve health and safety risks to the population of the United States.

When the Committee authorized the National Science Foundation budget for fiscal year 1980, it encouraged the NSF to sponsor systematic research to improve the methods for evaluation of the long-term comparative risks of alternative technological solutions, including inaction, to such national concerns as energy, materials, environmental quality, food or drugs. The Committee also asked the Foundation to promote education in risk assessment methods and to stimulate public and professional application of comparative risk research.

This Committee's Subcommittee on Science, Research and Technology has participated in numerous hearings and professional meetings dealing with the interdisciplinary field of risk analysis. In July

of 1979, a 2-day forum was sponsored jointly by this Subcommittee, the Senate Subcommittee on Science, Technology and Space, and the American Association for the Advancement of Science. This forum brought together experts from the Congress, academia, industry and government to discuss the potential application of risk/benefit analysis in such fields as energy policy, drug assessment and food safety, with particular emphasis on the legislative process.

In May of 1980, the Subcommittee on Science, Research and Technology held a 2-day hearing on Comparative Risk Assessment and on H.R. 4939, the "Risk Analysis Research and Demonstration Act of 1979," which had been introduced in July 1979 by Rep. Don Ritter, a Committee member at the time. This hearing elicited valuable testimony from witnesses with wide differences of opinion. The Subcommittee decided to withhold action on H.R. 4939 while making clear its continued interest in the emerging science of comparative risk assessment.

In October 1980, the Congressional Research Service conducted jointly with the Subcommittee a 2-day seminar entitled "Risk: Assessment, Acceptability and Management." The seminar addressed problems involved in defining and estimating the hazards of various technological activities and in determining the bases by which society can make risk acceptability decisions. It also examined different mechanisms for implementing risk acceptance decisions. The Committee studied the proceedings of the seminar and, so that they could be more widely discussed, ordered them issued as a formal Committee print.

Committee Hearings on H.R. 6159 and Its Predecessor, H.R. 3441

In May 1981, Mr. Ritter introduced (for himself, Mr. Fuqua and Mr. Brown of California) H.R. 3441, the "Risk Analysis Research and Demonstration Act of 1981." The Subcommittee held a hearing on the bill on September 24, 1981, and followed this up on March 17, 1982 by reporting it to the full Committee on Science and Technology with an amendment in the nature of a substitute. The clean bill became H.R. 6159 when Mr. Ritter (for himself, Mr. Fuqua, Mr. Walgren, and Mr. Brown of California) introduced it on April 26, 1982.

Committee Views

Risk assessment applications to food safety law

The Committee recognizes that federal health and safety regulations have often been criticized because insufficient data are available to formulate or support the regulatory requirements. As a result, regulations addressing health and safety risks arising from industrial activities or consumer use have frequently been controversial, inconsistent, and duplicative. To implement the many laws Congress has enacted requiring regulation of both naturally-occurring and technologically-caused risks, Federal regulatory agencies have had to make decisions regarding the nature and extent of particular risks arising under their respective regulatory authorities. These decisions have often involved assessments of risk. However, the comprehensiveness and quality of such risk assessments has varied, and regu-

latory actions based on them have correspondingly varied in effectiveness. Such uncertainty in quality may lead to wasteful "overkill" expenditures for toxicity testing or to unwisely lenient safety standards. Health and safety regulations based upon scientifically deficient risk analyses can also lead to frequent, complex, resource-draining litigation between regulating agencies and affected parties.

Even when risk analyses are carried out, agencies also attempt to take into account a number of economic, social, philosophical, and political considerations prior to formulating the specific requirement of proposed regulations, depending upon degree of regulatory flexibility allowed under the agency's legislative mandate. These broader considerations are certainly necessary and appropriate in forming public policy. The Committee supports this legislation only as a means to analyze the risk assessment component of regulatory decisions in the Federal Government with a view toward eventual coordination and improvement of risk assessment activities.

The risk analysis component should provide a disciplined approach to the collection and assessment of all the data pertinent to a reasoned decision. It should include the elements of uniformity and consistency necessary to facilitate evaluation and increase the predictability of the final decisions. The application of risk assessment to the regulatory decisions may also provide insight into the information which should be disseminated to consumers to allow for informed individual decisions.

Despite the clear advantages of well researched and well coordinated risk assessment procedures, there are some problems when risk assessment is applied to food safety regulations. Maintenance of safety of the food supply has long been one of the strongest felt public policy goals of our society. A standard of conservatism toward any compromise with absolute safety in judging appropriativeness of food additives has been recognized and affirmed for many years. Additives for convenience of commerce or marketing have had a severe burden of proof of safety impressed on them, and simple economic advantage has not been a justification of risk.

This conservatism is not based on philosophy alone. Rarely do we have available a complete toxicological or epidemiological basis on which to determine health risks associated with the use of a new additive or other food substance. Even if a precise assessment of health risks associated with particular regulatory actions could be determined, some method of evaluating those risks would have to be developed. Exactly how the government might do this is difficult to envision; life and health risks are difficult to evaluate.

The protection and formation of the public's health should remain the prime focus of food safety regulations. Regulatory decisions guided by risk assessment will be limited by the nature, quantity and quality of the scientic data available and the sophistication and appropriateness of the assessment methodology. In the interest of public health, the food safety decisionmaking process should allow for flexibility to address issues of uncertainty, to weigh the significance of scientific results, and to exercise scientific and other kinds of public policy judgment.

Therefore, the complexity of risk assessment in relation to food safety regulations leads the Committee to emphasize that this legislation should be used only to facilitate a coordinated research effort to examine and improve the use of risk assessment in a number of Federal agencies. It should not be construed as a legislative vehicle to imply Congressional approval for retreating from the historic conservatism of regulatory law for food safety, or for using risk assessment to reduce food industry responsibilities while increasing consumer risks.

Section-by-Section Analysis

SECTION 1

Section 1 designates the short title of the Act as the "Risk Analysis Research and Demonstration Act of 1982."

SECTION 2

Section 2 sets forth Congressional findings and declarations.

SECTION 3

Section 3 states the Act's purpose, which is to develop a coordinated research and demonstration program for risk analysis. Such a program would assess the current role of risk analysis in Federal regulatory decisionmaking, define criteria and standards to further its development and use, identify areas of research required to improve existing methodologies, and promote public awareness of the nature of regulated risks and the means of their quantification.

SECTION 4

Section 4 sets forth definitions of risk, risk assessment, risk evaluation, comparative risk-analysis, Administrator, Office, Director, and Federal regulatory agencies for the purposes of this Act.

SECTION 5

Section 5 describes the program objectives and assigns coordinating, planning, and implementation roles to the Office of Science and Technology Policy and OMB's Office of Information and Regulatory Affairs. Basically, the program will improve techniques for measuring, gathering and evaluating data necessary to complete risk assessments and evaluations, and will establish procedures for the sharing of risk analysis knowledge among and between Federal agencies and private sector entities. This section also describes the requirements for a program plan report to be submitted to the Congress in 12 months. Following enactment.

SECTION 6

Section 6 stipulates that Federal regulatory agencies shall recommend to OSTP research required to meet the Act's objectives.

SECTION 7

Section 7 specifies that prototypical risk analysis studies shall be undertaken by the relevant Federal agencies, and defines what these studies are intended to accomplish.

SECTION 8

Section 8 directs the Administrator as defined in Sec. 4 to submit a report to the Congress within 30 months following the Act's enactment into law that will include: (1) a summary and critical review of agencies' risk analysis procedures or capabilities as evidenced by the prototype studies to be performed under Sec. 7; (2) recommendations for legislative or nonlegislative changes for furthering the objectives of the Act; and (3) recommendations for improving the transfer of risk-related research and information, and for improving the public's appreciation of risk and regulatory decisions.

Committee Oversight Findings and Recommendations

Pursuant to Clause 2(l)(3), Rule XI of the Rules of the House of Representatives, under the authority of Clause 2(b)(1) and Clause 3(f), Rule X, the Committee's oversight findings and conclusions are reflected in the recommendations found in the present bill and report.

Summary of Committee on Government Operations Findings and Recommendations

Pursuant to Clause 2(b)(2), Rule X, and Clause 2(l)(3), Rule XI of the Rules of the House of Representatives, no findings or recommendations have been submitted by the Committee on Government Operations for inclusion in this report.

Congressional Budget Act Information

H.R. 6159 provides no new budget authority. Thus, the provisions of Section 308(a) of the Congressional Budget Act are not applicable.

Impact on Inflation

In accordance with Clause 2(l)(4), Rule XI of the Rules of the House of Representatives, the following statement is made concerning the inflationary impact of H.R. 6159.

H.R. 6159 is assessed to have no inflationary effect on prices and costs in the operation of the national economy. On the contrary, the research and demonstration program is expected to lead to improved approaches to Federal regulation in the fields of health and the environment, thereby reducing the inflationary impact of such regulation while preserving their overall benefit to human life.

Congressional Budget Office Cost Estimates

U.S. Congress,
Congressional Budget Office,
Washington, D.C., May 20, 1982.

Hon. Don Fuqua,
Chairman, Committee on Science and Technology, U.S. House of Representatives, Washington, D.C.

Dear Mr. Chairman: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has reviewed H.R. 6159, the Risk Analysis Research and Demonstration Act of 1982, as ordered reported by the House Committee on Science and Technology, May 13, 1982.

This bill seeks to improve the use of risk analysis by federal agencies that are responsible for regulatory decisions related to the protection of human life, health, and the environment. It requires nine federal agencies to undertake demonstration risk analysis projects, and directs the Office of Management and Budget to plan and implement an interagency program for improvement in the use of risk analysis. No additional appropriations are authorized for carrying out the provisions of the bill.

The greatest potential costs would be incurred by the nine agencies that would be required to undertake demonstration projects. The costs associated with these projects could be significant. However, the precise costs would depend on the specific analyses undertaken. Also, the agencies required to participate in the demonstration projects are already engaged in performing risk analysis. If these agencies use analysis that would have been conducted regardless of the requirements of this bill as demonstration projects, it is possible that there will be no significant cost associated with this provision of the bill. If, on the other hand, each agency undertakes an extensive additional risk analysis project, costs could be as great as $10 million or more, to be incurred during the fiscal years 1983 and 1984.

Other costs that will result from this bill are for report-writing and administrative activities that would be incurred primarily by the Office of Management and Budget, the Office of Science and Technology Policy, and the National Science Foundation. Costs for these activities are estimated to be approximately $100,000 in fiscal year 1983 and $50,000 each year in fiscal years 1984 and 1985. This is based on the assumption that two staff years would be required in fiscal year 1983, and one staff year each year in fiscal years 1984 and 1985. Smaller costs would be incurred in later years for administrative activities.

Sincerely,

Raymond C. Scheppach
(For Alice M. Rivlin, Director).

Committee Recommendation

A quorum being present, the Committee by voice vote ordered H.R. 6159 favorably reported on May 13, 1982.

Changes in Existing Law Made by the Bill, as Reported

In compliance with Clause 3 of Rule XIII of the Rules of the House of Representatives, it is hereby stated that no changes to existing law result from H.R. 6159.

Administration Actions

The Administration, as indicated in correspondence between OMB and Congressman Don Ritter, the bill's original sponsor, and from OMB to the Committee, is committed to the goal which underlies H.R. 6159 of improving the use of risk analysis. The staff of the Subcommittee on Science, Research and Technology met for several hours with representatives from OMB and the Office of Science and Technology Policy in their preparation of the legislation for the Subcommittee markup of March 17, 1982. In addition to the many minor differences which were reconciled at this meeting, it was also agreed to delete language pertaining to the authorization of appropriations to run the program in the amount of $1.7 million over two years. The conclusion was, and continues to be, that this effort was of sufficient importance that existing personnel at OMB and OSTP (particularly the former) would be made available to perform the duties required of these Offices in the administration of this legislation.

The Director of OMB has already used his authority under Executive Order 12291 (signed by the President on February 17, 1981) to issue uniform guidelines encouraging the use of risk analysis methods. Risk assessment techniques are required in regulatory impact statements (RIAs) whenever these techniques will contribute to more informed regulatory decisionmaking, according to OMB's written response to additional questions for the record at the hearing last September on this legislation.

On October 9, 1981, Vice President Bush announced that White House Science Advisor and OSTP Director George Keyworth would chair a newly formed Regulatory Work Group on Science and Technology. The new Work Group was placed organizationally under the Presidential Task Force on Regulatory Relief. Members of the Work Group include: the EPA Administrator, the FDA Commissioner, the Consumer Product Safety Commission Chairman, the Assistant Secretary of Labor for Occupational Safety and Health, and the Assistant Secretary of Agriculture for Marketing and Inspection. "The purpose of the Work Group," according to the press release from the Vice President, "is to strengthen the role of scientific data and analysis in the regulatory process. Science has come to play an increasingly important role in environmental, health and safety regulation in recent years. As a part of the Task Force's effort to improve the regulatory process, the Work Group will examine ways in which the agencies which have primary responsibility for these areas can work together

to enhance the scientific basis of their regulatory decisions. The Work Group will place particular emphasis on developing and applying techniques for quantifying and comparing risks of hazardous exposures."

The Administration excluded from this Work Group several other agencies which have some responsibility for regulatory decisions related to the protection of life, health and the environment. Thus, H.R. 6159 would mandate participation in the research and demonstration program by the following agencies that are not currently represented in a centrally coordinated working group for the improvement of risk analysis: the Nuclear Regulatory Commission, the Department of Transportation, the Department of Energy, and the Federal Aviation Administration.

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